DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 13, 2014

AMUSA
Mr. Alex Ferri
VP/GM of Operations
5209 Linbar Dr, Suite 640
Nashville, TN 37211

Re: K133685
Trade/Device Name: 0.9% Sodium Chloride Flush Syringe
Regulation Number: 21 CFR 880.5200
Regulation Name: Device, Flush, Vascular Access
Regulatory Class: II
Product Code: NGT
Dated: July 11, 2014
Received: July 15, 2014

Dear Mr. Ferri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, ″Misbranding by reference to premarket notification″ (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Enclosure

Indications for Use

Indications for Use Statement

510(k) Number (if known): K133685

Device Name: 0.9% Sodium Chloride Flush Syringe

Indications for Use:

"0.9% Sodium Chloride Flush Syringes are intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommendations of the manufacturer for the appropriate device".

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

510(k) Summary

As required by 809.92(a) (2).

510 (k) PREMARKET NOTIFICATION NUMBER: K133685

Submitter and Owner of the 510(k)

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Date of Preparation: 5/15/14

510(k) Application Number

Trade/Proprietary Name

0.9% Sodium Chloride Flush Syringe

Common Name/Usual Name

Saline Flush Syringe

Device Classification Name

Device, Flush, Vascular Access

Regulation Number

880.5200

Device Class

Class II Device

Classification Panel

General Hospital

Classification Product Code

NGT

THE PREDICATE DEVICE DESCRIPTION:

The Predicate Device, 510(k) Number: K120836 (AMUSA) consists of a non-sterile plastic 12 cc syringe filled with 3 mL, 5 mL, or 10 mL of 0.9% Sodium Chloride Flush Solution that is terminally sterilized. The predicate device is sterile on the outside and has a sterile fluid path. The Sterility Assurance Level (SAL) is 10^{-6}. This is a single use device. The solution contains no preservatives, or antimicrobial agents. No plasticizers, additives, crosslink agents, reagents, or surfactants were used during the manufacture of the syringes. The syringe may be used on a sterile field if packaging is not damaged and aseptic technique is used.

Indications For Use:

Intended use: 0.9% Sodium Chloride Flush Syringes are intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommendations of the manufacture for the appropriate device.

THE NEW DEVICE DESCRIPTION:

The new device, the subject of this 510(k), consists of a 20 mL, non-sterile plastic syringe filled with 20 mL of 0.9% Sodium Chloride Flush Solution USP that is terminally sterilized. The new device is sterile on the outside and has a sterile fluid path. The Sterility Assurance Level (SAL) is 10^{-6}. The syringe may be used on a sterile field if packaging is not damaged and aseptic technique is used. This is a single use device. The solution contains no preservatives, or antimicrobial agents. No plasticizers, additives, crosslink agents, reagents, colorants, inks, adhesives, surfactants, detergents, used during the manufacture of the syringes. The 20mL filled with 0.9% Sodium Chloride Flush Solution in a 20mL syringe is the only model which is subject to this 510(k). Other models previously cleared under 510K (K120836) consists of a non-sterile plastic 12 cc syringe filled with 3 mL, 5 mL, or 10 mL of 0.9% Sodium Chloride Flush Solution that is terminal sterilized.

Indications For Use:

Intended use: 0.9% Sodium Chloride Flush Syringes are intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommendations of the manufacture for the appropriate device.

TECHNILOGICAL/SUBSTANTIAL EQUIVALENCE SUMMARY: The technical characteristics for the new device do not differ from those of the currently marketed device. These devices have the same design, the same fundamental scientific and chemical characteristics, the same labeling, and have the same intended use. The differences in the proposed new device are an increase in the size and fill volume of the syringe. All other aspects of the product design remain the same. This device is categorized in ISO 10993-1:2009 as "External communicating device – blood path, indirect per section 5.2.2(a). The device will have limited contact of less than or equal to 24 hours. All materials contact the fluid path and are treated as indirect patient contact. The syringe device is fabricated from the following raw materials:

- Polypropylene homopolymer pellets (PF535)
- Dow Corning 360 Medical fluid
- West Pharmaceutical Rubber Plunger Tips
- Tip Cap Non-sterile Basell PF535 Polypropylene, Alpha Gray TPE G968B 4170

No other materials including plasticizers, additives, crosslink agents, reagents, colorants, inks, adhesives, surfactants, detergents, etc., are used during the manufacture of the syringes. The device does not use an energy source.

Technological/Substantial Equivalence Comparison Table:

Technological/Substantial Equivalence Table		
	Predicate Device	New Device
Intended Use	Intended use: 0.9% Sodium Chloride Flush Syringes are intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices.	Intended use: 0.9% Sodium Chloride Flush Syringes are intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices.
Design	Predicate device and new device have identical design.	New device has the same design as predicate.
Chemical Composition of Barrel	Non-sterile Polypropylene PF-535 Resin	Non-sterile Polypropylene PF-535 Resin
Chemical Composition of Plunger	Non-sterile Black Pharmaceutical Grade Rubber (Not made with Natural Rubber Latex)	Non-sterile Black Pharmaceutical Grade Rubber (Not made with Natural Rubber Latex)
Chemical Composition Tip Cap	Non-sterile Basell PF535 Polypropylene, Alpha Gray TPE G968B 4170	Non-sterile Basell PF535 Polypropylene, Alpha Gray TPE G968B 4170
Environment	Positive Differential Controlled and Monitored	Positive Differential Controlled and Monitored
Energy Source	There is not an energy source. The device is operated mechanically.	There is not an energy source. The device is operated mechanically.
Non-Pyrogenic	Entire device is nonpyrogenic	Entire device is nonpyrogenic
Additivies, latex, or preservatives	No additvities, natural rubber, or preservatives were used in the manufacture of the syringes.	No additvities, natural rubber, or preservatives were used in the manufacture of the syringes.
Sterile Barrier Package	Sterile barrier Pouch polypropylene film 3-6 mil	Sterile barrier Pouch polypropylene film 3-6 mil
Sterility Assurance Level	10-6	10-6
Sterility Labeling of Device	Fluid path and outside of device are sterile.	Fluid path and outside of device are sterile.
Sterilization Method	Gamma	Gamma
Expiry Dating	2 years	2 years
Filling Process	The filling process occurs in a positive differential, monitored, and controlled environment. The solution is contained in a sterile closed system.	The filling process occurs in a positive differential, monitored, and controlled environment. The solution is contained in a sterile closed system.
Equivalent Bench and Stability Testing	The predicate device Bench and Stability tests included: • Sterility • Pyrogen (LAL) analysis • pH • Water Loss • Iron • Heavy Metals • Sodium, Chloride • Particulate Matter	The same Bench and Stability tests were performed on the new device as the predicate device. Bench and Stability tests included: • Sterility • Pyrogen (LAL) analysis • pH • Water Loss • Iron • Heavy Metals • Sodium, Chloride • Particulate Matter
Size and Fill Volumes	3 mL/12 mL; 5 mL/12mL, 10 mL/12mL	20 mL/20 mL

Conclusion: The new device is identical to the predicate device in plastic materials composition, the form, and function (e.g. Flushing of vascular access devices). The two changes to the new device involve 1. Increase in syringe size from a 12 mL syringe to a 20 mL syringe and 2. Increase in the solution volume. Non-clinical verification testing for the proposed change involved chemical-physical, functional, and product stability testing. The results of testing conducted verify the new device performed in an equivalent manner to the predicate device. Therefore, the new device is substantially equivalent to the predicate device. Other companies have FDA 510(k) clearance for similar devices.